

AMENDMENT TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) An oral pharmaceutical dosage form comprising:

(a) a core material comprising ~~[that contains]~~ a proton pump inhibitor, at least one ~~[or more]~~ alkaline reacting compound ~~[compound(s)]~~ and optionally pharmaceutically acceptable excipients ~~[having]~~,

(b) a water soluble separating layer, and

(c) a ~~[an enteric]~~ coating layer comprising at least one enteric polymer,

wherein, [characterized in that] the core material is alkaline reacting, and upon application of the coating layer on the core material, [that] the separating layer is [being] formed in situ [during the enteric coating] as a water soluble salt product between the enteric polymer [coating layer polymer(s)] and the alkaline reacting compound [compound(s)].

2. (Currently amended) The [A] dosage form according to claim 1, wherein the alkaline reacting compound is [compounds are] selected from the group consisting of an alkaline reacting organic compound [substances], a hydroxide [hydroxides] of an alkali metal, an [metals or one of their] alkaline salt [salts] of phosphoric acid, an alkaline salt of carbonic acid, an alkaline salt of [or] silicic acid, and [or] an alkaline ammonium salt.

3. (Currently amended) The [A] dosage form according to claim 2, wherein the alkaline reacting compound [substance] is selected from the group consisting of a hydroxide of an alkali metal, [or] an alkaline salt of phosphoric acid, an alkaline salt of carbonic acid, an alkaline salt of [or] silicic acid, and [or] an alkaline ammonium salt.

4. (Currently amended) The [A] dosage form according to claim 2, wherein the alkaline reacting [compound is an alkaline] organic compound is [substance, e.g.] an amino acid or a salt thereof [an alkaline amine or a derivative thereof, or an alkaline salt of a weak organic acid].

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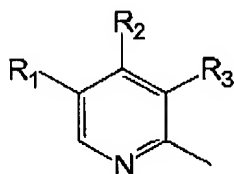
5. (Currently amended) **The [A]** dosage form according to claim 3 [2], wherein the [alkaline organic substance is an] amino acid is selected from the group consisting of [~~e.g.~~] lysine, arginine, ornithine and [~~or~~] histidine [~~or an alkaline amine or a derivative thereof, e.g., N-methyl-D-glucamine or trometamine~~].
6. (Currently amended) **The [A]** dosage form according to claim 1, wherein the alkaline reacting compound is [~~compounds are~~] present in a concentration of more than 0.1 mmol/g dry ingredients in the alkaline containing part of the core material.
7. (Currently amended) **The [A]** dosage form according to claim 1, wherein the enteric polymer is a [~~coating polymer(s) is/are~~] hydroxypropyl cellulose derivative [~~derivative(s), e.g., hydroxypropylmethylcellulose acetate succinate~~].
8. (Currently amended) **The [A]** dosage form according to claim 1, wherein the enteric coating polymer is a copolymer of methacrylic acid or methylmethacrylate ester [~~copolymerized methacrylic acid/methacrylic acid methyl esters~~].
9. (Currently amended) **The [A]** dosage form according to claim 1, wherein the proton pump inhibitor is a compound of the general formula I or a pharmaceutically acceptable salt thereof or a pure enantiomer thereof in neutral form or in the form of an alkaline salt



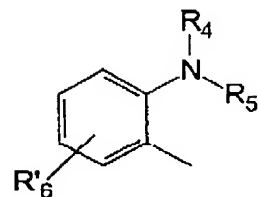
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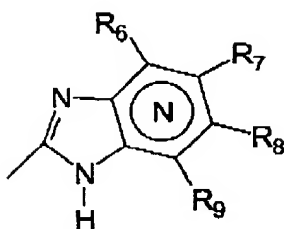
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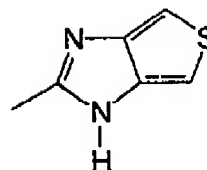
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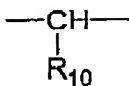
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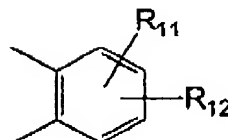
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X =



or



wherein N in the benzimidazole moiety means that one of the carbon atoms substituted by R₆-R₉ [optionally] may be exchanged for a nitrogen atom without any substituents;

R₁, R₂ and R₃ are the same or different and selected from the group consisting of hydrogen, alkyl, unsubstituted alkoxy, alkoxy [optionally] substituted by fluorine, alkythio, alkoxyalkoxy, dialkylamino, piperidino, morpholino, halogen, phenyl and phenylalkoxy;

R₄ and R₅ are the same or different and selected from hydrogen, alkyl and aralkyl;

R₆' is selected from the group consisting of hydrogen, halogen, trifluoromethyl, alkyl and alkoxy;

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R₆-R₉ are the same or different and selected from the group consisting of hydrogen, alkyl, alkoxy, halogen, halo-alkoxy, alkylcarbonyl, alkoxy carbonyl, oxazolyl, and trifluoroalkyl, or adjacent groups R₆-R₉ form ring structures which may be further substituted;

R₁₀ is hydrogen or forms an alkylene chain together with R₃ and

R₁₁ and R₁₂ are the same or different and selected from the group consisting of hydrogen, halogen, [or] alkyl and [alkyl groups,] alkoxy, which alkyl or alkoxy [groups and moieties thereof] may be branched or a [and] straight C₁-C₉-chain [chains] or a [comprise] cyclic alkyl [groups, for example cycloalkyl/alkyl].

10. (Currently amended) The [A] dosage form according to claim 1, wherein the proton pump inhibitor is omeprazole or an alkaline salt thereof.

11. (Currently amended) The [A] dosage form according to claim 1, wherein the proton pump inhibitor is a pure enantiomer of omeprazole or an alkaline salt thereof.

12. (Currently amended) The [A] dosage form according to claim 1, wherein the proton pump inhibitor is lansoprazole, one of its pure enantiomers or a pharmaceutically acceptable salt thereof.

13. (Currently amended) The [A] dosage form according to claim 1, wherein the proton pump inhibitor is pantoprazole, one of its pure enantiomers or a pharmaceutically acceptable salt thereof.

14. (Currently amended) The [A] dosage form according to claim 1, wherein the [alkaline reacting] core material is in the form of individual pellets [intended for a capsule formulation or a tableted multiple unit dosage form].

15. (Currently amended) The [A] dosage form according to claim 1, wherein the [alkaline reacting] core material is a tablet.

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16. (Currently amended) **The** [A] dosage form according to claim 14 [+], wherein individually enteric coated pellets are compressed into a tableted multiple unit dosage form.

17. A process for the preparation of an oral, enteric coated pharmaceutical dosage form comprising the steps of:

forming a core material comprising [that contains] a proton pump inhibitor, at least one [or more] alkaline reacting compounds and optionally pharmaceutically acceptable excipients, and applying a coating layer comprising at least one enteric polymer so as to surround the core material thereby forming in situ [having a water soluble] separating layer as a water soluble product between the alkaline compound and the enteric polymer [and an enteric coating layer characterized in that an alkaline reacting core material is prepared and coated with an enteric coating polymer wherein a separating layer between the core material and the enteric coating layer is formed in situ by a reaction between the enteric coating polymer(s) and the alkaline reacting compound(s) in the core material during the application of the enteric coating onto the alkaline reacting core material].

18. (Canceled) ~~An oral, pharmaceutical dosage form comprising a proton pump inhibitor as defined in any of claims 1-16 for use in inhibiting gastric acid secretion in mammals and man.~~

19. (Currently amended) A method for inhibiting gastric acid secretion comprising [in mammals and man by] administering [to a host in need thereof a dosage form comprising] a therapeutically effective amount of a dosage form [dose of a proton pump inhibitor] as defined in any of claims 1-16 to a patient in need thereof.

20. (Canceled) ~~Use of an oral pharmaceutical dosage form defined in any of claims 1-16 for the manufacture of a medicament useful in the treatment of gastric acid related diseases.~~

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21. (New) The dosage form according to claim 2, wherein the alkaline reacting organic compound is an alkaline amine or a derivative thereof.

22. (New) The dosage form according to claim 21, wherein the derivative of the alkaline amine is N-methyl-D-glucamine or trometamine.

23. (New) The dosage form according to claim 2, wherein the alkaline reacting organic compound is an alkaline salt of a weak organic acid.

24. (New) The dosage form according to claim 7, wherein the hydroxypropyl cellulose derivative is hydroxypropylmethylcellulose acetate succinate.